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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,162	ALTHAUS, HARALD	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/03; 7/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-14 are pending.

2. Applicant's election with traverse of Group 1, Claims 1-12 and 14 (now claims 1-14) drawn to an antibody that binds selectively to carbohydrate deficient transferring, and antigen binding fragment thereof, a process of making said antibody, a kit comprising said antibody and an immunoassay for detecting CDT in a sample using said antibody, filed 10/6/05, is acknowledged. The traversal is on the ground that a search and examination of an immunoassay for detecting carbohydrate deficient transferring using the same antibody can be made without undue burden. Upon reconsideration, the group 2 has been rejoined with group 1. Therefore, the requirement of Group 1 (now claims 1-14) is still deemed proper and is therefore made FINAL.

3. Claims 1-14, drawn to drawn to an antibody that binds selectively to carbohydrate deficient transferring, and antigen binding fragment thereof, a process of making said antibody, a kit comprising said antibody and an immunoassay for detecting CDT in a sample using said antibody, are being acted upon in this Office Action.

4. Claims 1 and 4 are objected to because "An antibody" should have been "An isolated antibody".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridomas DSM ACC2540 and DSM ACC2541 are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

It is noted that said hybridomas were deposited under the Budapest Treaty (page 3-4 of specification), an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridomas secreting said antibodies have been deposited under the Budapest Treaty and that the hybridomas will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808.

7. Claims 1-7 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an isolated antibody or binding fragment thereof that binds specifically to human carbohydrate deficient transferrin (CDT) consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4 in aqueous solution; (2) the said isolated antibody is a monoclonal antibody; (3) a process of making the antibody or binding fragment thereof that binds specifically to human carbohydrate deficient transferrin (CDT) consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4 by immunizing a suitable experimental animal with unglycosylated human carbohydrate deficient transferrin (CDT), fusing the spleen cells of the experimental animal with the myeloma cells, selecting the hybrid cells that produce the antibody which specifically binds to human carbohydrate deficient transferrin (CDT) consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4 and isolating said antibody; (4) an immunoassay for detecting human carbohydrate deficient transferrin (CDT) in a sample which comprises contacting a sample with the isolated antibody or binding fragment thereof that binds specifically to human carbohydrate deficient transferrin (CDT) consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4, and detecting qualitatively or quantitatively the formation of an immune complex with the human carbohydrate deficient transferrin (CDT), and (5) a test kit for carrying out an immunoassay comprising the isolated antibody or binding fragment thereof that binds specifically to human carbohydrate deficient transferrin (CDT) consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4, **does not** reasonably provide enablement for (1) any antibody, any antibody such as any monoclonal antibody which binds to any carbohydrate deficient transferrin (CDT) other than human carbohydrate deficient transferrin (CDT), (2) any antibody which binds "insubstantially" to the "peptides P or P2" prepared according to EP-0605627, (3) any antibody which binds

"insubstantially" to the peptides P or P2 prepared according to EP-0605627 whose "binding behavior" has been established in relation either to solid phase-bound peptides P1 or P2 or any peptides P1 or P2 present in aqueous solution, (4) any antibody which selectively to any CDT as set forth in claims 5-6, (5) any immunoassay for detecting any CDT in a sample using any antibody mentioned above, (6) any kit for carrying out any immunoassay using any antibody mentioned above, and (7) a process of preparing any antibody mentioned above by immunizing an animal with any unglycosylated transferrin mentioned above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only two monoclonal antibodies and binding fragment thereof that bind specifically to human carbohydrate deficient transferrin. The said monoclonal antibodies are produced by immunizing an animal with unglycosylated human transferrin (CDT) and selecting the antibodies that bind specifically to the peptide consisting of the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4.

The specification does not teach how to make any antibody that binds to any and all carbohydrate deficient transferrin (CDT) because there is insufficient guidance as to binding specificity of any and all antibodies that bind to any carbohydrate deficient transferrin (CDT). The specification discloses only unglycosylated human transferrin (CDT) and does not disclose any other unglycosylated transferrin (CDT), much less which epitope the claimed antibody binds.

There is insufficient guidance and objective evidence as to how to make any antibodies that bind to any carbohydrate deficient transferrin (CDT) other than the human carbohydrate deficient transferrin (CDT), in turn, would be useful for detecting human carbohydrate deficient transferrin (CDT) from alcoholic human serum.

There is insufficient guidance to direct a person of skill in the art to select particular sequences as essential for making antibody that binds specifically to any and all carbohydrate deficient transferrin (CDT). A person of skill in the art could not predict which particular amino acid sequences of which carbohydrate deficient transferrin (CDT) are essential and could be used for making antibody that binds specifically to the discontinuous epitopes of the claimed antibody.

It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds can result in substantially different binding specificity.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Since the binding specificity of the antibody for the claimed method is not enabled, it follows that the monoclonal antibody, the kit comprising the undisclosed antibody and an immunoassay for detecting CDT in a sample using the undisclosed antibody is not enabled.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

8. Claims 1-7 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any antibody, any antibody such as any monoclonal antibody which binds to any carbohydrate deficient transferrin (CDT) other than human carbohydrate deficient transferrin (CDT), (2) any antibody which binds "insubstantially" to the "peptides P or P2" prepared according to EP-0605627, (3) any antibody which binds "insubstantially" to the peptides P or P2 prepared according to EP-0605627 whose "binding behavior" has been established in relation either to solid phase-bound peptides P1 or P2 or any peptides P1 or P2 present in aqueous solution, (4) any antibody which selectively to any CDT as set forth in claims 5-6, (5) any immunoassay for detecting any CDT in a sample using any antibody mentioned above, (6) any kit for carrying out any immunoassay using any antibody mentioned above, and (7) a process of preparing any antibody mentioned above by immunizing an animal with any unglycosylated transfferin.

The specification discloses only two monoclonal antibodies and binding fragment thereof that bind specifically to human carbohydrate deficient transferring consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4. The said monoclonal antibodies are produced by immunizing an animal with unglycosylated human transferrin (CDT) and selecting the antibodies that bind specifically to the peptide consisting of the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4.

With the exception of the specific antibody and binding fragment thereof that binds specifically to human unglycosylated transferrin peptide consisting of the amino acid sequence of SEQ ID NO: 1-4, there is insufficient written description about the binding specificity of all antibody as broadly as claimed. Other then the human unglycosylated transferrin, the specification does not disclose any other unglycosylated transferrin, let alone the antibody produced by immunizing human unglycosylated transferrin could bind to any other carbohydrate deficient transferring having discontinuous epitopes. The specification discloses only two monoclonal antibodies produced by hybridomas having the deposited number DSM ACC2540 and DSM ACC2541 that bind to discontinuous epitopes on human carbohydrate deficient transfferin consisting of the amino acid sequence of SEQ ID NO: 1-4. There is inadequately written description about the structure of the immunogen to direct a person of skill in the art to select particular sequences as essential for making antibody that binds specifically to any and all carbohydrate deficient transferrin (CDT) having a discontinuous epitopes of the claimed antibody.

The specification discloses only human carbohydrate deficient transferrin to which the claimed antibody binds, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of carbohydrate deficient transferrin and antibody that binds to any and all carbohydrate deficient transferrin to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "which binds insubstantially" in claim 2 is indefinite and ambiguous because the specification does not define "insubstantially". One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The "binding behavior" in claim 3 is indefinite and ambiguous because it is not clear which binding behavior is part of the claimed invention. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The term "CDT" in claim 4 is indefinite and ambiguous. While abbreviation can be used in a claim, to avoid potential confusion, the first recitation of the abbreviation should be preceded by the full terminology, such as carbohydrate deficient transferrin (CDT), for example.

The "peptides P1 and P2" in claims 2 and 3 are ambiguous and indefinite without the amino acid sequence. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The "region" in claims 5-6 are is indefinite and ambiguous because it is not clear which "region" in the segments (1) to (4) to which the antibody binds is part of the claimed invention. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 7, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0605 627 B1 (May 19, 1999; PTO 1449).

The EP 0605 627 B1 patent teaches various antibodies such as polyclonal, monoclonal antibody and binding fragment thereof that binds selectively to human unglycosylated transferrin (CDT) (carbohydrate deficient transferrin (CDT) in aqueous solution such as body fluid of alcoholic patient (see page 7, paragraph 0035, claims 1-9, and 13-14, in particular). A product is a product, irrespectively of the intended use of an antibody "without the latter (CDT) needing to be bound to a solid phase". The reference antibody is made by a process by immunizing an animal with the reference peptide P1 or P2 of SEQ ID NO: 2, and 1, respectively, fusing the spleens cells of the animal with myeloma cells, cloning the hybrid cells, selecting the hybrid cells which produces the reference antibody and obtaining the antibody produced by the hybridoma using a process known to one skill in the art (see page 19, claim 19, page 10-11, page 8, lines 1-26, in particular). Claim 2 is included in this rejection because the term "binds insubstantially to the Claim 2 means the claimed antibody still binds to the reference peptide P1 or P2, albeit to a minor extent or still (cross reactive). The reference further teaches how to characterized the binding behavior of the reference antibody to the reference peptides P1 or P2 that bound to a solid phase (see page 13, Example 4, in particular) or in aqueous solution such as unglycosylated transferrin (CDT) in serum sample of alcoholic patient (see page 13, Table 2, page 8, paragraph 0047, in particular). The EP 0605 627 B1 patent teaches an immunoassay for detecting CDT in a sample using the reference antibody (see paragraph bridging page 8 and 9, claim 13-16 of the reference, in particular). The EP 0605 627 B1 patent teaches a kit for carrying an immunoassay using the reference antibody (see claim 17 of the EP 0605 627 B1 patent, in particular). Thus, the reference teachings anticipate the claimed invention.

13. Claims 1-3, 7, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO93/06133 (April 1993; PTO 1449).

The WO93/06133 publication teaches various antibodies such as polyclonal, monoclonal antibody and binding fragment thereof that bind selectively to human unglycosylated transferrin (CDT) (carbohydrate deficient transferrin (CDT) in aqueous solution such as body fluid of alcoholic patient (see entire document, page 18, claims 1-6, pages 24-25, in particular). A product is a product, irrespectively of the intended use of an antibody such as "without the latter (CDT) needing to be bound to a solid phase". The reference antibody is made by a process by immunizing an animal with the reference peptide P1 or P2 having the same amino acid sequences as that disclosed in EP-0605627 (see page 14, reference SEQ ID NOS: 1 and 2, page 15, lines 3, in particular), fusing the spleens cells of the animal with myeloma cells, cloning the hybrid cells, selecting the hybrid cells which produces the reference antibody and obtaining the antibody produced by the hybridoma using a process known to one skill in the art (see page 17-18, in particular). Claim 2 is included in this rejection because the term "binds insubstantially" to the Claim 2 means the claimed antibody still binds to the reference peptide P1 or P2, albeit to a minor extent or still (cross reactive). The reference further teaches how to characterized the binding behavior of any antibody to the reference peptides P1 or P2 that bound to a solid phase (see page 38-40, in particular) or in aqueous solution such as unglycosylated transferrin (CDT) in serum sample of alcoholic patient (see page 13, Table 2, page 8, paragraph 0047, in particular). The WO93/06133 publication teaches an immunoassay for detecting CDT in a sample using the reference antibody (see paragraph bridging page 19-20, claim 18-21 of the reference, in particular). The WO93/06133 publication teaches a kit for carrying an immunoassay using the reference antibody (see claim 22 of the WO93/06133 publication, page 21, in particular). Thus, the reference teachings anticipate the claimed invention.

14. Claims 1-3, 7, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 5,702,904 (Dec 30, 1997; PTO 892).

The '904 patent teaches various antibodies such as polyclonal, monoclonal antibody and binding fragment thereof that binds selectively to human unglycosylated transferrin (CDT) (carbohydrate deficient transferrin (CDT) in aqueous solution such as body fluid of alcoholic patient (see col. 12-13, col. 16, Table 16, claims 1-8, in particular). A product is a product, irrespectively of the intended use of an antibody such as "without the latter (CDT) needing to be bound to a solid phase". The reference antibody is made by a process by immunizing an animal with the reference peptide P1 or P2, fusing the spleens cells of the animal with myeloma cells,

cloning the hybrid cells, selecting the hybrid cells which produces the reference antibody and obtaining the antibody produced by the hybridoma using a process known to one skill in the art (see col. 17, Immunization of Mice, col. 18, Production of Hybridoma, in particular). Claim 2 is included in this rejection because the term "binds insubstantially to the Claim 2 means the claimed antibody still binds to the reference peptide P1 or P2, albeit to a minor extent or still (cross reactive). The reference further teaches how to characterized the binding behavior of the reference antibody to the reference peptides P1 or P2 that bound to a solid phase (see col. 16, Example 4, in particular) or in aqueous solution such as unglycosylated transferrin (CDT) in serum sample of alcoholic patient (see col. 16, Table 2, page col. 19, in particular). The '904 patent teaches an immunoassay for detecting CDT in a sample using the reference antibody (see col. 9, lines 47-67, claim 25-26 of the '904 patent, in particular). The '904 patent teaches a kit for carrying an immunoassay using the reference antibody (see claims 27-28 of the '904 patent, col. 11, lines 1-30, in particular). Thus, the reference teachings anticipate the claimed invention.

15. Claims 1, 7, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/36418 (June 22, 2000; PTO 1449).

The WO 00/36418 publication teaches an antibody or binding fragment thereof that binds to carbohydrate deficient transferrin (CDT) (see claim 14 of WO 00/36418, page 25, lines second paragraph, in particular). The WO 00/36418 publication further teaches an immunoassay for detecting CDT in sample using the reference antibody in a kit such as dipstick (see abstract, claims of WO 00/36418 publication, in particular). A product is a product, irrespectively of the intended use of an antibody "without the latter (CDT) needing to be bound to a solid phase". Thus, the reference teachings anticipate the claimed invention.

16. Claims 4, 8-9 and 12 are free of prior art.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

19. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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